Attorney's Docket No. 8789-49CT PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Leonard Continuation of Serial No.: 10/147,366
Serial No.: To Be Assigned
Filed: Concurrently Herewith
For: TREATMENT OF CONDITIONS RELATING TO HORMONE DEFICIENCIES BY ADMINISTRATION OF PROGESTINS

Date: October 3, 2003

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Attached is a list of documents on form PTO-1449. All items listed on the PTO-1449 were cited in parent application Serial No. 10/147,366; filed May 16, 2002. Since the benefit of this application is claimed under 35 U.S.C. §120, no copies need to be furnished in accordance with 37 C.F.R. §1.98(d); however, copies will be furnished on request. It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.56 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

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Clara R. Beard

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)	Attorney Docket Number 8789-49CT	Serial No. To Be Assigned
	Applicants: Leonard.	
	Filing Date Concurrently Herewith	Group To Be Assigned

U. S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	RE 36,247	07/1999	Plunkett et al.			
	2.	5,891,867	04/1999	Lanquetin et al.			
	3.	5,827,843	10/1998	Koninckx			
	4.	5,208,225	05/1993	Boissonneault et al.			
	5.	5,108,995	04/1992	Casper			
	6.	5,043,331	08/1991	Hirvonen et al.			
	7.	5108995	4/1992	Casper			
	8.	5,935,949	8/1999	White			
	9.	4,425,339	01/1984	Pitchford			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes | No
	10.	WO 98/06404	2/1998	WIPO			
	11.	WO 00/74684	12/2000	WIPO			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	12.	Simon et al., *Unscheduled Bleeding During Initiation of Continuous Combined Hormone Replacement Therapy: A Direct Comparison of Two Combinations of Norethindrone Acetate and Ethinyl Estradiol to Medroxyprogesterone Acetate and Conjugated Equine Estrogens*, Menopause, The Journal of the North American Menopause Society, Vol. 8, No. 5, 2001, pp. 321-327
	13.	Pickar et al., *Endometrial Effects of Lower Doses of Conjugated Equine Estrogens and Medroxyprogesterone Acetate*, Fertility and Sterility, Vol. 76, No. 1, July 2001, pp. 25-31
	14.	Chesnut et al., *A Randomized Trial of Nasal Spray Salmon Calcitonin in Postmenopausal Women With Established Osteoporosis: The Prevent Recurrence of Osteoporotic Fractures Study*, The American Journal of Medicine, Vol. 109, September 2000, pp. 267-276
	15.	Archer et al., *Effects of Lower Doses of Conjugated Equine Estrogens and Medroxyprogesterone Acetate On Endometrial Bleeding*, Fertility and Sterility, Vol. 75, No. 6, June 2001, pp. 1080-1087
	16.	Dawson et al., *A Randomized Study Comparing Standard Versus Moderately High Dose Megestrol Acetate for Patients With Advanced Prostate Carcinoma*, Cancer, Vol. 88, No. 4, February 15, 2000

EXAMINER _____ DATE CONSIDERED

*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		pp. 825-834
	17.	Farinha et al., *Improved Bioavailability of a Micronized Megestrol Acetate Tablet Formulation in Humans*, Drug Development and Industrial Pharmacy, Vol. 26, No. 5, 2000, pp. 567-570
	18.	Naing et al., *Megestrol Acetate Therapy and Secondary Adrenal Suppression*, Cancer, Vol. 86, No. 6, September 15, 1999, pp. 1044-1049
	19.	Bernhard et al., *Quality of Life in Postmenopausal Patients With Breast Cancer After Failure of Tamoxifen: Formestane Versus Megestrol Acetate as Second-Line Hormonal Treatment*, European Journal of Cancer, Vol. 35, No. 6, 1999, pp. 913-920
	20.	Loprinzi et al., *Randomized Comparison of Megestrol Acetate Versus Dexamethasone Versus Fluoxymesterone for the Treatment of Cancer Anorexia/Cachexia*, Journal of Clinical Oncology, Vol. 17, No. 10, October 1999, pp. 3299-3306
	21.	Engelson et al., *Effects of Megestrol Acetate and Testosterone on Body Composition in Castrated Male Sprague-Dawley Rats*, Nutrition, Vol. 15, No. 6, 1999, pp. 465-473
	22.	Critchley et al., *Effects of Estrogen and Progesterone on the Endometrium*, Estrogens and Progestagens in Clinical Practice, edited by Fraser et al., 1998, pp. 145-161
	23.	Ross et al., *Endometrial Effects of Three Doses of Trimegestone a New Orally Active Progestogen, On the Postmenopausal Endometrium*, Maturitas, Vol. 28, 1997, pp. 83-88
	24.	Conard et al., *Cardiovascular Risk Factors and Combined Estrogen-Progestin Replacement Therapy: A Placebo-Controlled Study With Nomegestrol Acetate and Estradiol*, Fertility and Sterility, Vol. 64, No. 5, November 1995, pp. 957-962
	25.	Sturdee et al., *Is the Timing of Withdrawal Bleeding a Guide to Endometrial Safety During Sequential Oestrogen-Progestagen Replacement Therapy?*, The Lancet, Vol. 334, October 8, 1994, pp. 979-982
	26.	Von Roenn, *Randomized Trials of Megestrol Acetate for AIDS-Associated Anorexia and Cachexia*, Oncology, Vol. 51, Suppl 1, 1994, pp. 19-24
	27.	Espie, *Megestrol Acetate in Advanced Breast Carcinoma*, Oncology, Vol. 51, Suppl 1, 1994, pp. 8-12
	28.	Loprinzi et al., *Megestrol Acetate for the Prevention of Hot Flashes*, The New England Journal of Medicine, Vol. 331, No. 6, August 11, 1994, pp. 347-352
	29.	Sporrong et al., *A Novel Statistical Approach to Analysis of Bleeding Patterns During Continuous Hormone Replacement Therapy*, Maturitas, Vol. 11, 1989, pp. 209-215
	30.	Schacter et al., *Megestrol Acetate: Clinical Experience*, Cancer Treatment Reviews, Vol. 16, 1989, pp. 49-63
	31.	Sporrong et al., *Comparison of Four Continuously Administered Progestogen Plus Oestradiol Combinations for Climacteric Complaints*, British Journal of Obstetrics and Gynaecology, Vol. 95, October 1988, pp. 1042-1048
	32.	Alexieva-Figusch et al., *Treatment of Metastatic Breast Cancer Patients With Different Dosages of Megestrol Acetate; Dose Relations, Metabolic and Endocrine Effects*, Eur J Cancer Clin Oncol, 1984, pp. 33-40
	33.	Canetta et al., *Megestrol Acetate*, Cancer Treatment Reviews, Vol. 10, 1983, pp. 141-157
	34.	Whitehead et al., *Actions of Progestins on the Morphology and Biochemistry of the Endometrium of Postmenopausal Women Receiving Low-Dose Estrogen Therapy*, Am M Obstet Gynecol Vol

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		142, No. 6, March 15, 1982, pp. 791-795
	35.	*Megestrol Acetate*, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Vol. 21, 1979, pp. 431-439
	36.	Donkervoort et al., *Megestrol Acetate in Treatment of Benign Prostatic Hypertrophy*, Urology, Vol. VI, No. 5, November 1975, pp. 580-587
	37.	Tisell et al., *Androgenic Properties and Adrenal Depressant Activity of Megestrol Acetate Observed in Castrated Male Rats*, Acta Endocrinologica, Vol. 78, 1975, pp. 316-324
	38.	Burke et al., *Megestrol Acetate for Estrus Postponement in the Bitch*, JAVMA, Vol. 167, No. 4, pp. 285-287
	39.	Wait, *Megestrol Acetate in the Management of Advanced Endometrial Carcinoma*, Obstetrics and Gynecology, Vol. 41, No. 1, January 1973, pp. 129-136
	40.	Balin et al., *Low Dosage Megestrol Acetate Application as Contraceptive*, The Journal of Reproductive Medicine, Vol. V, No. 1, July 1979, pp. 74-81
	41.	Cooper et al., *The Metabolism of Megestrol Acetate (17 ∀-Acetoxy-6-Methylpregna-4,6-Diene-3,20-Dione) in Women*, Steroids, Vol. 11, No. 2, February 1968, pp. 133-149
	42.	International Search Report corresponding to PCT/US 02/15690 mailed on May 12, 2002.
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